



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of DIGGANS *et al.*

Confirmation No.: 1710

Serial No.: 10/580,423

Group Art Unit: 1631

Filed: May 24, 2006

Examiner: To Be Assigned

For: METHODS FOR MOLECULAR TOXICOLOGY MODELING

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INFORMATION DISCLOSURE STATEMENT TRANSMITTAL

Enclosed is an Information Disclosure Statement and accompanying Form PTO/SB/08 for the above-identified patent application.

☒ In accordance with 37 C.F.R. §1.97(b), no additional fee for submission of the IDS is required.

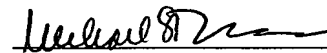
The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§1.16, 1.17, and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 50-1283.

Dated: 3-22-07

Respectfully submitted,
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**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §1.97(b)**

In accordance with the duty of disclosure set forth in 37 C.F.R. §1.56, Applicant(s) hereby submits the following information in conformance with 37 C.F.R. §§1.97 and 1.98.

- [X] Pursuant to 37 C.F.R. §1.98, a copy of each non-US patent document cited in the attached Form PTO/SB/08 is enclosed.
- [X] No copies of any U.S. patents or U.S. patent application publications listed on the attached Form PTO/SB/08 are being provided pursuant to 37 C.F.R. §1.98.
- [X] The present application and its related applications generally disclose toxicology modeling of various tissues or cells, *e.g.*, heart, kidney, liver, or primary hepatocytes using gene expression data. As such, some of the nucleic acid sequences disclosed in this application may overlap with those disclosed in other related applications. For the Examiner's convenience, a list of the co-pending applications is presented below.

APPLICATION SERIAL NO.	TITLE	APPLICATION DATE	TISSUE
09/917,800	Molecular Toxicology Modeling	July 31, 2001	Liver
10/501,933	Molecular Hepatotoxicology Modeling	Jan. 31, 2003	Liver

APPLICATION SERIAL NO.	TITLE	APPLICATION DATE	TISSUE
11/059,535	Molecular Toxicology Modeling	Feb. 17, 2005	Liver
10/152,319	Molecular Toxicology Modeling	May 22, 2002	Kidney
10/515,325	Molecular Nephrotoxicology Modeling	Nov. 24, 2003	Kidney
11/036,196	Molecular Toxicology Modeling	Jan. 18, 2005	Kidney
11/642,647	Molecular Nephrotoxicology Modeling	Dec. 21, 2006	Kidney
10/338,044	Molecular Cardiotoxicology Modeling	Jan. 8, 2003	Heart
10/541,937	Molecular Cardiotoxicology Modeling	Jan. 8, 2004	Heart
11/600,759	Cardiotoxin Molecular Toxicology Modeling	Nov. 17, 2006	Heart
10/357,507	Primary Rat Hepatocyte Toxicology Modeling	Feb. 4, 2003	Hepatocyte
10/515,373	Primary Rat Hepatocyte Toxicity Modeling	Aug. 9, 2004	Hepatocyte
10/580,423	Methods For Molecular Toxicology Modeling	Nov. 24, 2004	General
11/547,759	Hepatotoxicity Molecular Models	Apr. 7, 2005	Liver

[X] In particular, the following publications were cited by the U.S. Patent Examiner in U.S. application 09/917,800:

1. U.S. 5,811,231
2. U.S. 6,372,431
3. U.S. 6,218,122
4. Lashkari *et al.* PNAS, vol. 94: 13057-13062, 1997

[X] The following publications were cited by the Examiner in U.S. application 10/152,319:

1. "nephrotoxic" definition, Merriam-Webster online dictionary, 2005, on the world wide web at <http://www.m-w.com/cgi-bin/dictionary?Book=Dictionary&va=nephrotoxic>

2. Yamaki *et al.* Cellular mechanism of lithium-induced nephrogenic diabetes insipidus in rats. American Journal of Physiology Renal Physiology, 1991. Vol. 261, F505-F511

[X] The following publication was cited by the Examiner in U.S. application 10/301,856:

1. Konstandi *et al.* Stress-mediated modulation of B(alpha)P-induced hepatic CYP1A1: role of catecholamines, 2004 Chemico-Biological Interactions, vol. 147

[X] The following publication was cited by the Examiner in U.S. application 10/191,803:

U.S. 6,461,807

[X] The following publications were cited by the Examiner in U.S. application 10/357,507:

1. U.S. 6,203,987
2. Peng *et al.* JBC, 271(6):3324-3327
3. GenBank Acc. No. AA799479 (4/30/1998)
4. GenBank Acc. No. AI177366 (1/20/1999)
5. GenBank Acc. No. M25823 (4/27/1993)
6. GenBank Acc. No. AA891812 (1/25/1999)

[X] References were also cited in related or corresponding foreign applications. The following publications were cited in a foreign search or examination report corresponding to PCT/US01/23872.

1. Raburn *et al.*, "Stage-specific expression of B Cell Translocation Gene 1 in rat testis," Endocrinology 136(12):5769 - 5777, 1995
2. GenBank Accession No. L26268, Raburn *et al.*, "Rattus norvegicus anti-proliferative factor (BTG1) mRNA," January 26, 1996
3. Bissig *et al.*, "Functional expression cloning of the canalicular sulfate transport system of rat hepatocytes," J Biol. Chem 269(4):3017-3021, 1994
4. GenBank Accession No. L23413, Bissig *et al.*, "Rattus norvegicus sulfate anion transporter (sat-1) mRNA," April 12, 1994
5. WO 00/12760

6. Farr *et al.*, "Concise review: gene expression applied to toxicology," *Toxicol Sci* 50(1):1-9, 1999
7. Nuwaisyr *et al.*, "Microarrays and toxicology: the advent of toxicogenomics," *Molecular Carcinogenesis* 24(3):153 - 159, 1999

[X] References were also cited in related or corresponding foreign applications. The following publications were cited in a foreign search or examination report corresponding to PCT/US02/21735.

1. US 2001/0039006 A1
2. US 2002/0119462 A1
3. Grigg *et al.* Environmental Health Institute to use gene chips to evaluate chemicals for potential harm to humans. NIEHS, 29 February 2000
4. US 6,228,589

[X] The following publications were cited in a foreign search or examination report corresponding to EP 01959321.9.

1. Markovich *et al.*, "Heavy metals mercury, cadmium, and chromium inhibit the activity of the mammalian liver and kidney sulfate transporter sat-1," *Toxicol. Appl. Pharmacol.* 154:181-187 (1999)
2. WO 99/58670
3. WO 93/01205
4. WO 99/43345
5. Berbner *et al.*, "induction of cytochrome P450 1A and NDA damage in isolated rainbow trout (*Onchorhynchus mykiss*) hepatocytes by 2, 3, 7, 8-tetrachlorodibenzo p-dioxin," *Biomarkers* 4: 214-228 (1999)
6. Bogdan, "Human carbon catabolite repressor protein (CCR4)-associative factor 1: cloning, expression and characterization of its interaction with the B-cell translocation protein BTG1," *Biochem. J.* 336:471-481 (1998)

[X] The following publications were cited in a foreign search or examination report corresponding to PCT/US03/03194:

1. U.S. 6,218,122
2. U.S. 2001/0049139

[X] The following publications were cited in a foreign search or examination report corresponding to Canadian application 2,447,357

1. WO 01/32928, 05/11/01, Far *et al.*
2. Fielden *et al.* Changes and limitations of gene expression profiling in mechanistic and predictive toxicology, *Toxicol. Sci.* 60: 6-10
3. Affymetrix Rat Toxicology U34 Datasheet, released 08/99

[X] The following publications were cited in a foreign search or examination report corresponding to EP 02771863.4

1. WO 01/32928, 05/10/2001
2. Database Geneseq [online], "Sindbis virus genomic cDNA PCR primer SEQ ID NO:3," Database Accession No. AAZ92894, retrieved from EBI Accession No. GSN:AAZ92894 (2000)
3. Bulera, S.J., *et al.*, RNA expression in the early characterization of hepatotoxins in wistar rats by high-density DNA microarrays. *Hepatology*, 33:1239-1258, (2001)
4. Nuwaisyr *et al.*, "Microarrays and toxicology: the advent of toxicogenomics," *Molecular Carcinogenesis* 24(3):153-159, 1999.
5. Burczynski *et al.*, Toxicogenomics-based discrimination of toxic mechanism in hepg2 human hepatoma cells. *Toxicol. Sci.*, 58: 399-415 (2000)
6. Burchiel *et al.*, Analysis of genetic and epigenetic mechanisms of toxicity potential roles of toxicogenomics and proteomics in toxicology. *Toxicol. Sci.*, 59: 193-195 (2001)
7. WO 97/13877
8. WO 01/25473
9. WO 99/27090

[X] The following publications were cited in a foreign search or examination report corresponding to PCT/US02/16173:

1. U.S. 6,228,589
2. U.S. 6,365,352
3. U.S. 6,403,778
4. Kim *et al.*, Fumonisin B1 induces apoptosis in LLC-PK1 renal epithelial cells via a sphinganine and calmodulin dependent pathway. *Toxicology and Applied Pharmacology* 176:118-126 (2001)
5. Yang *et al.*, Differential regulation of COX-2 expression in the kidney by lipopolysacc: role of CD14. *Am J Physiology* 277(1):F10-F16 (1999)

6. Pfeffer *et al.*, Xanthine dehydrogenase and xanthine oxidase activity and gene expression in renal epithelial cells. *J Immunology* 153(4):1789-1797 (1994)

[X] The following publications were cited in a foreign search or examination report corresponding to PCT/US03/37556:

1. U.S. Publication 2002/0142284, 10/03/2002, Raha *et al*
2. WO 94/17208
3. WO 97/13877

[X] The following publications were cited in a foreign search or examination report corresponding to EP 02806804.7

1. WO 01/32928, 05/10/2001
2. Database Geneseq [online], "Sindbis virus genomic cDNA PCR primer SEQ ID NO:3," Database Accession No. AAZ92894, retrieved from EBI Accession No. GSN:AAZ92894 (2000)
3. Bulera, S.J., *et al.*, RNA expression in the early characterization of hepatotoxicants in wistar rats by high-density DNA microarrays. *Hepatology*, 33:1239-1258, (2001)
4. Nuwaisyr *et al.*, "Microarrays and toxicology: the advent of toxicogenomics," *Molecular Carcinogenesis* 24(3):153-159, 1999.
5. Burczynski *et al.*, Toxicogenomics-based discrimination of toxic mechanism in hepg2 human hepatoma cells. *Toxicol. Sci.*, 58: 399-415 (2000)
6. Burchiel *et al.*, Analysis of genetic and epigenetic mechanisms of toxicity potential roles of toxicogenomics and proteomics in toxicology. *Toxicol. Sci.*, 59: 193-195 (2001)
7. WO 97/13877
8. WO 01/25473
9. WO 99/27090

[X] The following publications were cited in a foreign search or examination report corresponding to PCT/US04/025646:

1. Wilson, *et al.* Exploring drug-induced alterations in gene expression in mycobacterium tuberculosis by microarray hybridization. *PNAS* 96:12833-12838 (1999)

2. Tao, *et al.*, Profiling of differently expressed apoptosis-related genes by cDNA arrays in human cord blood DC34+ cells treated with etoposide. *Experimental Hematology*, 31:251-2606 (2003)
3. Cadet, *et al.*, Distinct gene expression signatures in the striata of wild-type and heterozygous c-fos knockout mice following methamphetamine administration, *Synapse*, 44:211-2268 (2002)
4. He *et al.*, Histone deacetylase inhibitors induce remission in transgenic models of therapy-resistant acute promyelocytic leukemia., *J. Biol. Chem.*, 276: 20858-20865 (2001)

[X] The following publications were cited in a foreign search or examination report corresponding to PCT/US04/039593:

1. U.S. Publication 2003/0124552, 07/03/2003, Lindemann *et al*
2. U.S. 6,132,969, 02/17/2000, Stoughton *et al.*
3. U.S. 2003/0154032, 08/14/2003, Pittman *et al.*
4. U.S. 2003/0028327, 02/06/2003, Brunner *et al.*
5. Hasegawa *et al.* *Gan To Kagaku Ryoho* 30: 325-33 (abstract)

[X] The following publications were cited in a foreign search or examination report corresponding to PCT/US05/034780:

1. Boorman *et al.*, "Toxicogenomics, Drug Discovery, and the Pathologist," *Toxicologic Pathology* 30(1):15-27 (2002).
2. Harris *et al.*, "Comparison of basal gene expression profiles and effects of hepatocarcinogens on gene expression in cultured primary human hepatocytes and HepG2 cells," *Mutation Research* 539:79-99 (2004).
3. Gooderham *et al.*, "Molecular and genetic toxicology of 2-amino-1-methyl-6-phenylimidazo[4,5-*b*]pyridine (PhIP)," *Mutation Research* 506-507:91-99 (2001).
4. Hogstrand *et al.*, "Application of genomics and proteomics for study of the integrated response to zinc exposure in a non-model fish species, the rainbow trout," *Comparative Biochemistry and Physiology Part B* 133:523-535 (2002).

[X] The following publications were cited in a foreign search or examination report corresponding to PCT/US05/011532:

1. Kikuchi *et al.* Gene expression and activities of protein phosphatases 1 alpha, 2A, 2C in hepatocarcinogenesis and regeneration after partial hepatectomy. Cancer detection and prevention. 1997 vol.21(1): 36-43
2. Frazier *et al.* Predictive toxicodynamics: empirical/mechanistic approaches. Toxicology in Vitro, 1997, vol. 11: 465-472
3. Irizarry *et al.* Summaries of Affymetrix Gene Chip probe level data. Nucleic Acids Research, 2003, vol. 31, page e15
4. U.S. 6,153,421
5. U.S. 6,421,612
6. U.S. 5,858,659
7. Jakubczak *et al.* An oncolytic adenovirus selective for retinoblastoma tumor suppressor protein pathway-defective tumors. Cancer Research, 2003 vol 63:1490-1499

This Information Disclosure Statement is filed within any one of the following time periods:

- ☐ within three months from the filing date of this application;
- ☐ within three months from the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in this international application;
- ☒ before the mailing date of a first office action on the merits; or
- ☐ before the mailing of a first office action after the filing of a request for continued examination under 37 C.F.R. § 1.114.

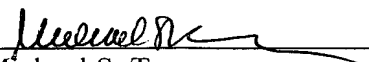
It is respectfully requested that the Examiner consider the above-noted information and return an initialed copy of the attached Form PTO/SB/08 to the undersigned.

Respectfully submitted,
COOLEY GODWARD KRONISH LLP

Dated: 3-22-07

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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Complete if Known	
		Application Number	10/580,423
		Filing Date	May 24, 2006
		First Named Inventor	DIGGANS
		Group Art Unit	1631
Examiner Name	To Be Assigned		
Sheet	1 of 27	Attorney Docket Number	GENE-120/02US

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code (if known)		
	1.	5,811,231		Farr et al.	09-22-1998
	2.	5,858,659		Sapolsky et al.	01-12-1999
	3.	6,132,969		Stoughton et al.	02-17-2000
	4.	6,153,421		Yanagi et al.	11-28-2000
	5.	6,203,987		Friend et al.	03-20-2001
	6.	6,218,122		Friend et al.	04-17-2001
	7.	6,228,589		Brenner et al.	05-08-2001
	8.	6,365,352		Yerramilli et al.	04-2-2002
	9.	6,372,431		Cunningham et al.	04-16-2002
	10.	6,403,778		Cunningham et al.	06-11-2002
	11.	6,421,612		Agrafiotis et al.	07-16-2002
	12.	6,461,807		Friend et al.	10-8-2002
	13.	2001/0039006		Snodgrass	11-8-2001
	14.	2001/0049139		Lagasse et al.	12-6-2001
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	16.	2002/0142284		Raha et al.	11-3-2002
	17.	2003/0124552		Lindemann et al.	07-03-2003
	18.	2003/0154032		Pittman et al.	08-14-2003
	19.	2003/0028327		Brunner et al.	02-06-2003

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	T
		Office	Number	Kind Code (if known)			
	20.	WO	93/01205		The Salk Institute for Biological Studies	1-21-1993	
	21.	WO	94/17208		Xenometrix, Inc.	4-08-1994	
	22.	WO	97/13877		Lynx Therapeutics, Inc.	04-17-1997	
	23.	WO	99/27090		Smithkline Beecham Corporation	06-03-1999	
	24.	WO	99/43345		Eisai Co., Ltd.; Beth Israel Deaconess Medical Center	09-02-1999	
	25.	WO	99/58670		Cadus Pharmaceuticals Corporation	11-18-1999	
	26.	WO	00/12760		Incyte Pharmaceuticals	9-3-2000	
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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Complete if Known	
		Application Number	10/152,319
		Filing Date	05/22/2002
		First Named Inventor	MENDRICK
		Group Art Unit	1631
		Examiner Name	C.L. Smith
Sheet	2 of 27	Attorney Docket Number	GENE-077/22US

	27.	WO	01/32928		Phase-I Molecular Toxicology	05-10-2001	
	28.	WO	01/25473		Source Precision Medicine, Inc.	04-12-2001	

OTHER – NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	29.	"nephrotoxic" definition, Merriam-Webster online dictionary, 2005, on the world wide web at http://www.m-w.com/cgi-bin/dictionary?book=Dictionary&va=nephrotoxic , 2 pages
	30.	Aardema and MacGregor, Mutation Res., 499:13-25, (2002)
	31.	Adamson & Harman et al., Biochem. Pharmacol., 45: 2289-2294 (1993)
	32.	Affymetrix Rat Toxicology U34 Datasheet, released 08/99
	33.	Afshari et al., Cancer Res., 59: 4759-4760 (1999)
	34.	Agha et al., Lipid Peroxidation and Lysosomal Integrity ; 31., 279-285 (1995)
	35.	Ahotupa et al., Carcinogenesis., 15: 863-868 (1994)
	36.	Ala-Kokko, et al., Biochem. J., 244:75-79, (1987)
	37.	Al-Bayati & Stohs, Arch. Environ. Contam. Toxicol., 20: 361-365 (1991)
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	39.	Amelsen, Jean Claude., Setting death in motion , Vol., (1998)
	40.	Andersen & Barton, Environ. Health Perspect., 106: 349-355 (1998)
	41.	Anderson et al., Toxicol. Appl. Pharmacol., 137: 75-89 (1996)
	42.	Anderson, Steven P., Hepatic Expression of Acute-Phase Protein, 26: 226-238 (1999)
	43.	Andersson et al; Anthraquinone-induced cell injury; 135: 11-20 (1999)
	44.	Anton et al., Cell Biochem. Biophys., 32: 27-36 (2000) Abstract only
	45.	Arano et al ., Arzneim-Forsch./Drug, 46 : 398-400 (1996)

Examiner Signature 48526 v1/DC	Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Unique citation designation number (optional). ²See attached Kinds of U.S. Patent Documents. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.
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		Application Number	10/152,319
		Filing Date	05/22/2002
		First Named Inventor	MENDRICK
		Group Art Unit	1631
		Examiner Name	C.L. Smith
Sheet	3 of 27	Attorney Docket Number	GENE-077/22US

OTHER – NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	46.	Atchison et al., Digestive Dis. Sci., 45: 614-620 (2000)
	47.	Bajgar et al., Neurochem. Int., 24: 555-558 (1994)
	48.	Baker et al., Chem. Res. Toxicol., 14(9): 1218-1231 (2001)
	49.	Bandara, et al., Toxicol. Sci., 73:195-206, (2003)
	50.	Barner & Gray, Ann. Pharmacother., 32: 70-77 (1998)
	51.	Bartosiewicz et al., J. Pharmacol. Exp. Ther., 297: 895-905 (2001)
	52.	Beck et al, Arch. Toxicol., 64: 210-217 (1990)
	53.	Becker et al., Alzheimer Dis. Assoc. Disord., 10: 124-131 (1996)
	54.	Bedard et al., Antimicrob. Agents Chemother., 43: 557-567 (1999)
	55.	Bedossa et al., Hepatology, 19: 1262-1271 (1994)
	56.	Beierschmitt, William P., Induction of Hepatic Microsomal Drug-Metabolizing,, 15-21
	57.	Belury et al., Toxicol. Appl. Pharmacol., 151: 254-261 (1998)
	58.	Berbner et al., "induction of cytochrome P450 1A and NDA damage in isolated rainbow trout (Onchorhynchus mykiss) hepatocytes by 2, 3, 7, 8-tetrachlorodibenzo p-dioxin," Biomarkers 4: 214-228 (1999)
	59.	Bergeron et al., Xenobiotica, 28: 303-312 (1998)
	60.	Berndt et al., Proc. Natl. Acad. Sci. U.S.A., 95: 12556-12561 (1998)
	61.	Birge et al., Toxicol. Appl. Pharmacol., 105: 472-482 (1990)
	62.	Bissig et al., "Functional expression cloning of the canalicular sulfate transport system of rat hepatocytes," J Biol Chem 269(4):3017-3021, 1994.
	63.	Boelsterli et al., Cell Biol. Toxicol., 3: 231-250 (1987)
	64.	Boess, et al., Toxicological Sciences, 73:386-402, (2003)

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		Filing Date	05/22/2002
		First Named Inventor	MENDRICK
		Group Art Unit	1631
		Examiner Name	C.L. Smith
Sheet	4 of 27	Attorney Docket Number	GENE-077/22US

OTHER – NON PATENT LITERATURE DOCUMENTS		
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		First Named Inventor	MENDRICK
		Group Art Unit	1631
		Examiner Name	C.L. Smith
Sheet	17 of 27	Attorney Docket Number	GENE-077/22US

OTHER – NON PATENT LITERATURE DOCUMENTS		
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		First Named Inventor	MENDRICK
		Group Art Unit	1631
		Examiner Name	C.L. Smith
Sheet	24 of 27	Attorney Docket Number	GENE-077/22US

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